

REMARKS

Claims 13-27, 36-48, 67 and 75-103 are pending in the application. Claims 13-27, 36-48, and 67 have been withdrawn from consideration. Claims 75, 78, 80-82, 84-87, and 98 are currently amended. Claims 79, 90-97, and 99-103 are canceled. After entry of the present amendment, claims 75-78, 80-89, and 98 remain under consideration.

Applicants respectfully request reconsideration of the present application for the reasons that follow.

Examiner Interview Summary

Applicants thank the Examiner for courtesies extended in a telephonic interview with applicants' representatives Heather Gerard, Michael Slater, and Lynda Fitzpatrick on December 23, 2010 ("the telephone interview"). During the telephone interview, the outstanding obviousness rejections were discussed. The Examiner indicated that certain arguments and amendments to the claims may result in the withdrawal of the rejections. Such arguments and amendments have been put forth below. Applicants appreciate the Examiner's time in conducting the telephone interview.

Claim Objection

Claim 82 received an objection due to numbering error and has been renumbered to address the objection.

Rejections Under 35 U.S.C. § 103(a)

Claims 75-103 were rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,248,569 issued to Dunn et al. ("Dunn") in view of U.S. Patent No. 5,342,782 issued to Thach, Kappelman et al. (1995) *Gene*, 160:55-98 ("Kappelman"), and the New England Biolabs Catalog. Applicants respectfully submit that these rejections should be withdrawn as follows.

Independent Claim 75

As amended, independent claim 75 requires *SgfI* as the first restriction enzyme and *PmeI* or *EcoI*CR1 as the second restriction enzyme. The Examiner alleges that "the placement of any restriction site, in any vector or DNA sequence, was obvious to one of ordinary skill in the art."

Final Action of 10/07/2010 ("Final Action") at 4-5. A statement so broad reaches beyond the scope of plausible support and loses sight of the claimed subject matter actually at issue. Claim 75 does not generically claim a class of vectors comprising any restriction site. Instead, the issue is whether the cited references render obvious the specific combination of restriction enzyme recognition sites recited in claim 75: a first recognition site for *SgfI* that is 5' to a second recognition site for *PmeI* or *EcoICRI*.

In this regard, the Examiner has failed to establish that the cited references taught or suggested the claimed combination of restriction enzymes. The MPEP makes clear that an objective reason to combine reference teachings is required to establish obviousness.

"A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art' at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references."

MPEP § 2143.01 (emphasis in original).

More than 3,000 type II restriction enzymes have been described. Absent some concrete motivation, it is thus highly unlikely that one of skill in the art would have honed in on these particular restriction enzymes, among the thousands available, for use with the vector of claim 75. Yet the Examiner has not pointed to any reason why one of ordinary skill in the art would select *SgfI* with *PmeI* or *EcoICRI* for use with the claimed vectors, nor is any such motivation present in the cited references. Accordingly, Applicants respectfully submit that a prima facie case of obviousness has not been established.

Moreover, even assuming, *arguendo*, that a *prima facie* case of obviousness were to be established by the Examiner, Applicants respectfully submit that Applicants achieved unexpected and surprising results that are sufficient to overcome any such *prima facie* case. Attached hereto is a declaration under 37 C.F.R. § 1.132 signed by inventor Dr. Michael Slater ("the Declaration"). In the Declaration, Dr. Slater indicates that "the claimed vectors work unexpectedly well in facilitating cloning without the need to purify the DNA fragment of interest." Declaration at 1. Dr. Slater provides data showing the percent efficiencies achieved using vectors that fall within the scope of the claimed invention. See Appendix of the Declaration.

Plasmid maps of vectors pF1A – pF8A are provided in the appendix, accompanying the data for those vectors. Cloning reactions 1-20 indicate separate experiments performed using the

indicated combinations of vector and DNA fragment source. The DNA fragment sources pF1K-LacZ α – pF5K-LacZ α each contained a DNA fragment including a fragment open reading frame encoding LacZ and flanked by recognition sites. Thus, the indicated cloning experiments were performed as follows: (1) digestion of the vector with *SgfI* and either *PmeI* or *EcoICRI*, (2) digestion of the fragment source with *SgfI* and *PmeI*, (3) ligation of the restriction fragments, (4) transformation of cells, and plating transformed cells on agar plates. Since the fragment open reading frame encodes LacZ, blue/white screening was used to calculate the cloning efficiency in each reaction. See Section 5 and the Appendix of the Declaration.

Dr Slater states that “[a] similar protocol was used for each of the cloning reactions in the Appendix” and that “cloning reaction 1... was conducted using vector pF5A cut with *SgfI* and *PmeI*, and the DNA fragment was obtained by digesting pF1K-LacZ α with *SgfI* and *PmeI*. The resulting restriction products were ligated, used to transform competent cells, and plated in triplicate on agar plates containing X-gal. The number of blue colonies and total colonies were counted on each plate to determine the transfer frequency of the cloning reaction.” See Declaration at 6, and Appendix A of the Declaration.

In view of these data, Dr. Slater avers that “the cloning efficiencies achieved are surprising, and much higher than would be expected with this type of cloning.” Declaration at 2. Dr. Slater explains that the unexpectedly high transfer frequencies offer “significant advantages both in terms of minimizing the number of colonies that must be screened to find a desired clone and also facilitating the capture of scarce or low-yield DNA fragments of interest.” Declaration at 2. Thus, the claimed vectors yielded unexpectedly robust cloning efficiencies that offer significant advantages by streamlining cloning procedures.

Accordingly, the applicants’ claimed vectors offer significant and unexpected advantages, which are sufficient to overcome a *prima facie* case of obviousness. Allowance of claim 75 is therefore respectfully requested.

Dependent Claims 76-78, 80-89, and 98

Claims 76-78, 80-89, and 98 depend directly or indirectly from independent claim 75 and are therefore allowable for at least the reasons discussed above. Allowance of these claims is therefore respectfully requested.

CONCLUSION

In view of the foregoing, applicants respectfully request allowance of the claims under consideration. Should any questions remain, the Examiner is encouraged to contact the undersigned at the number below.

Respectfully submitted,

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